FDA Preliminary Public Health Notification*: Vail Products Enclosed Bed Systems

Updated: March 30, 2005

Original date: March 25, 2005

On March 22, the Food and Drug Administration (FDA) and the U.S. Department of Justice, initiated a seizure of all Vail model 500, 1000, and 2000 enclosed bed systems made by Vail Products, Inc., of Toledo, Ohio, because patients can become entrapped and suffocate.

The seizure action was taken at the Toledo manufacturer of beds not yet shipped. FDA expects the firm to take action to address safety issues with these same models that have already been distributed to hospitals, nursing homes or private homes.

Vail enclosed bed systems are canopy-like padded beds covered with nylon netting that is zipped into place. They are used for at risk patients, both adults and children, with cognitive impairment, unpredictable behavior, spasms, seizures, and other disorders. The beds are used as an alternative to a physical or drug restraint to reduce falls from a bed and prevent patients from wandering.

Approximately 5,000 of these beds have been distributed nationwide. FDA is aware of approximately 30 adverse event reports, including at least 7 deaths, resulting from entrapments, falls, and other incidents. More than half of the 30 incidents that occurred involved children age 16 and under.

The Vail 500, 1000, and 2000 beds can be identified by a Vail label containing a model number. The label is on the front of the bed or on the leg of the bed.

FDA will update this Notification as more information becomes available.

Recommendation for Users

FDA is advising hospitals, nursing homes and consumers who have a Vail 500, 1000 or 2000 enclosed bed system to stop using it immediately and move the patient to an alternate bed. Facilities that have engineers available should check the beds for possible entrapment zones in all possible bed positions. Entrapment zones can include, but are not limited to, areas between the side rails and mattress, between the mattress and canopy in places where the rails do not extend, and areas between the end rails and mattress..

If continued use of the bed is the only option, at this time Vail Products recommends that users take the following safety precautions:

- For the Vail 1000 models only: the Hi-Lo feature allows the entire bed sleep surface to be raised and lowered. When in the "Hi" position, patients can become entrapped. **Never leave the Hi-Lo feature in the high position while the patient is unattended.**

- **Always leave the side rails in the "Up" position** in both models except when you are moving the patient from the bed.

- To reduce the possibility of entrapment between the bed rails and the mattress for all models, **use only the mattress recommended by the manufacturer.**

- For the Vail 1000 and 2000 models only: If you have received a retrofit kit, make sure it is properly installed.

Note: These beds should not be used for extremely violent, aggressive, combative or suicidal patients or patients who have multiple lines.

Reporting Adverse Events to FDA

FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect that a reportable adverse event was related to the use of a Vail enclosed bed system, you should follow the reporting procedure established by your facility.

We also encourage you to report adverse events related to Vail enclosed bed systems that do not meet the requirements for mandatory reporting. You can report these directly to the device manufacturer. You can also report to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch by phone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787; or online at http://www.fda.gov/medwatch/report.htm. Consumers can also report directly to MedWatch.

Getting More Information

For further details on the seizure, see FDA's 3/22/05 Talk Paper at: www.fda.gov/bbs/topics/ANSWERS/2005/ANS01347.html.

For questions regarding the information in this notification, contact Vail Products, Inc., Customer Service Dept. at 1-800-235-8245.

If you have questions for FDA, please contact the Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, Fax at 301-594-2968, or by e-mail at phann@cdrh.fda.gov. You may also leave a voice mail message at 301-594-0650 and we will return your call as soon as possible.

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Sincerely yours,

Daniel G. Schultz, MD
Director
Center for Devices and Radiological Health
Food and Drug Administration

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